

REMARKS

Claims 35-54 are pending.

DOUBLE PATENTING REJECTION

Claims 35-38 are rejected on the ground of non-statutory obvious-type double patenting over claims 1 and 4 of US Patent No. 6,358,924. Applicant inadvertently did not include the terminal disclaimer in their previous response. Applicant herewith submits a terminal disclaimer over US Patent No. 6,358,924. As such, Applicant submits the rejection is moot and requests withdrawal.

35 U.S.C. 112 REJECTION

Applicant submits that the present rejection is ambiguous. The Examiner alleges that Claims 35-54 are rejected under 35 U.S.C. 112, first paragraph as failing to comport with written description. The Examiner has set forth an analysis discussing the factors set forth in *In re Wands*. (858 F.2d 731, 737). Applicant submits that such an analysis is appropriate for a rejection under the enablement requirement of 35 U.S.C. 112, first paragraph and not for written description. The written description requirement is separate and distinct from the enablement requirement. *Vascath, Inc., v Mahhurkar*, 935 F.2d 1555, 1563. Applicant will address the Examiner's concerns with respect to written description.

The Examiner appears to allege that the Applicant has described the terms "GLP-1, GLP-1 analogs and GLP-1 derivatives" by function and not the structure of the compounds. (Page 4-5, Paper No.20070615)

To satisfy the written description requirement, "the disclosure must convey must . . . convey with reasonable clarity to those skilled in the art that . . . [the inventor] was in possession of the invention." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d. 1320, 1323.

Applicant respectfully submits the application complies with the written description requirement as Applicant has provided sufficient disclosure of actual GLP-1 analogs and derivatives, (not mere functional definitions) to convey with reasonably clarity that the Applicants were in possession of the claimed invention.

The present invention is directed to a formulation comprising GLP-1, GLP-1 analogs and GLP-1 derivatives, a tween polymeric surfactant, a buffer and a preservative. Applicant has defined these terms using structural features starting on page 7, line 19. For example, GLP-1 analogs are defined as having "one or more amino acid substitutions, deletions, inversions, or additions compared to GLP-1." (Specification, page 7, lines 24-26). In addition, pages 7-12 provide examples of many GLP-1 analogs and derivatives. Specifically, page 9, line 26 through page 10 discloses a specific large genus of GLP-1 analogs which can also be derivatized. Thus, the Applicant has not merely relied on functional definitions to describe the terms "GLP-1, GLP-1 analogs and GLP-1 derivatives." Applicant has provided structural information in defining these terms and thus, Applicant submits, the written description requirement has been met.

Conclusion

Applicant believes that the rejections submitted by the Examiner have been traversed and respectfully ask that the Examiner allow all pending claims.

Respectfully submitted,

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